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Chlordecone (Kepone): Position Document 4

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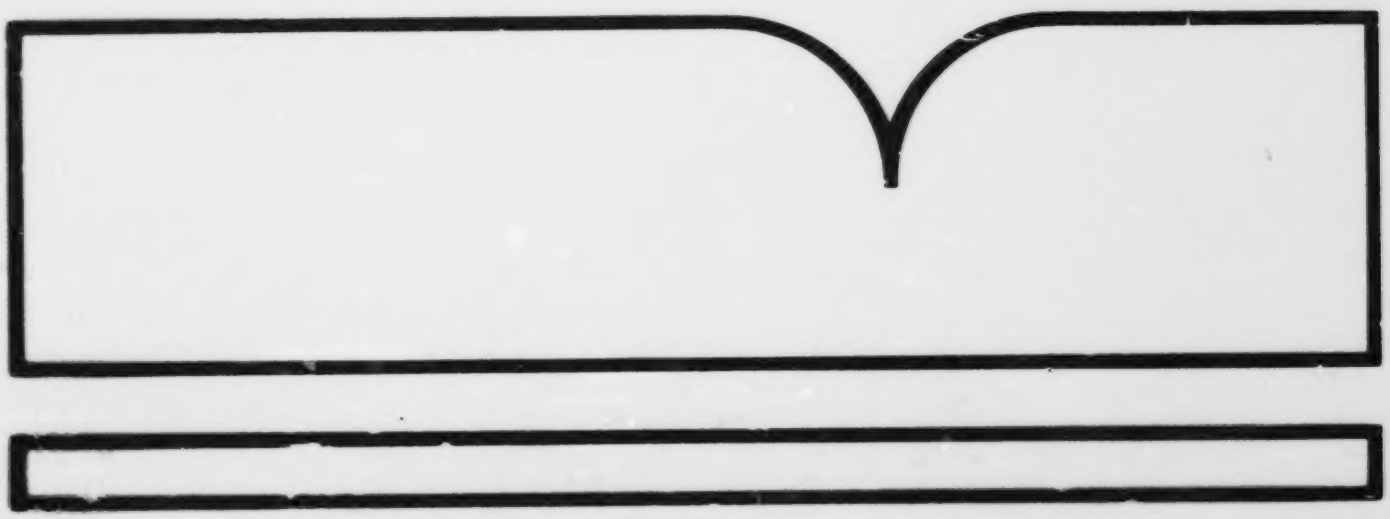

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16. Abstract (Limit: 200 words)

This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

17. Document Analysis a. Descriptors

PESTICIDES, STANDARDS, REGULATIONS, MANUFACTURING, CHEMISTRY, TOXICOLOGY, RESIDUES, ECOLOGY, PATH OF POLLUTANTS

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Kepone Working Group
Environmental Protection Agency

I. BACKGROUND

On March 19, 1976, the Deputy Assistant Administrator for Pesticide Programs issued a "Notice of Presumption Against Continued Registration of Pesticide Products" containing chlordecone (Kepone) published in the Federal Register March 25, 1976 (41 FR 12333). The Notice of Presumption was based on studies which demonstrated that chlordecone induces oncogenic effects in experimental mammalian species as a result of oral exposure. The Agency received comments from six registrants and other interested parties. None of these comments contested the validity of the studies upon which the presumption was based. Several submissions, which did not attempt to demonstrate lack of risk due to chlordecone, urged that the Agency merely allow use of existing stocks of manufacturing grade 25% Kepone Special Mixture (EPA Reg. No. 218-544) already in the hands of formulators for a predetermined period of time. Those comments which did address the risk issue attempted to demonstrate that, when considered in connection with widespread and commonly recognized practices of use, chlordecone will not concentrate, persist, or accrue to levels in man or the environment likely to result in any significant chronic adverse effects.

Allied Chemical Company, holder of 12 Kepone (chlordecone) registrations, including the manufacturing-use-only registrations, did not attempt to rebut the presumption. Rather, Allied requested that its registrations be voluntarily cancelled pursuant to Section 6(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (86 Stat. 973, 89 Stat. 751, 7 U.S.C. 136 et seq.). On June 9, 1976, the Deputy Assistant Administrator for Pesticide Programs responded to their request by issuing a notice of cancellation of all Allied registrations for chlordecone products (41 FR 24624). According to the terms of that notice, the registrations of those products are now cancelled.[1/]

After reviewing the recommendations of the Agency's technical staff based on a review and analysis of rebuttal attempts, and after a complete benefit/risk evaluation of the use of registered pesticide products containing chlordecone, the Deputy Assistant Administrator for Pesticide Programs approved a proposed "Notice of Intent to Cancel Registrations of Pesticide Products Containing Chlordecone (Kepone)." This proposed notice of intent would have cancelled the remaining registrations of all registered products containing chlordecone. With regard to existing stocks of chlordecone, the proposed notice would have

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1/ By letter of February 4, 1977, the EPA Office of Enforcement formally requested that Allied Chemical Corporation voluntarily recall all stocks of its manufacturing use and end-use products containing chlordecone, for which registration was cancelled by the Notice of June 9, 1976.

allowed sale, distribution, and use of all existing stocks of "inaccessible" products,[2] but would prohibit sale, distribution, or use of existing stocks of "accessible" products.[3] Position Document 3 (developed by the Office of Special Pesticide Reviews) set forth the scientific and policy rationale for the proposed notice of intent to cancel, and recommended that registrants of inaccessible products be permitted to use existing stocks of manufacturing-use-only 25% Kepone (Special Mixture) to formulate additional inaccessible traps for a period of three years. The proposed notice of intent to cancel reflected this determination. In addition, because the June 9, 1976, Section 6(a)(1) notice cancelling Allied's registration for manufacturing grade chlordecone did not provide for use of existing stocks, a separate notice was prepared which, in effect, would have rescinded the July 9 notice to the extent that the amended notice would have allowed for use of certain existing stocks of manufacturing grade chlordecone.

These notices, and supporting documents, were presented to the FIFRA Scientific Advisory Panel and the United States Department of Agriculture (USDA) on December 10, 1976. Both groups have commented on the notices. This position document contains EPA's response to the comments of the Scientific Advisory Panel and the Secretary of Agriculture and is intended to constitute the response mandated by section 6(b)(1) of FIFRA as amended.

2/ Inaccessible products are defined as all enclosed traps made from metal or plastic, as well as metal stakes containing chlordecone which are hammered into the ground.

3/ Accessible products are defined as those which would be removed from their containers, as well as foil- or cardboard-covered traps.
held by formulators and dispose of it in a safe manner.

II. SUMMARY OF EXTERNAL REVIEW COMMENTS

A. Response of the FIFRA Scientific Advisory Panel (SAP)

The Scientific Advisory Panel submitted its final report to this Agency on January 13, 1977 (1). The Panel stated that, in addition to the carcinogenic effects of chlordecone, the Agency should have considered existing information on other adverse health effects, e.g., neuromuscular, behavioral, reproductive, and mutagenic effects. The Panel also expressed concern with regard to the disposal of the manufacturing-use-only and end-use products.

The recommendations of the Scientific Advisory Panel listed below were unanimously agreed to unless otherwise noted.

(1) The Agency should cancel all uses of chlordecone within 30 days.

(2) The Agency should allow sale and use of existing stocks of inaccessible chlordecone products for a period of up to 3 years from the effective date of cancellation.[4/]

(3) The Agency should recover Allied 25% Kepone Special Mixture (EPA Reg. No. 218-544) presently held by formulators and dispose of it in a safe manner.[5/]

4/ Minority comment: The minority opinion was in opposition to this recommendation and cited further contamination of the environment by the spread of the bait material by insects and the waste disposal of traps.

5/ Minority comment: One member disagreed but believed that because some risk to formulators may exist, formulating processes should be monitored by the appropriate federal agency in order to provide for the safety of the workers and their families.

(4) The Agency should limit the quantity of inaccessible bait products containing chlordecone which can be formulated, distributed, or sold during the 3-year period extending from the effective date of cancellation to that quantity which can be formulated from supplies on hand as of the effective date of cancellation. (This recommendation appears to be in direct conflict with recommendation (3) above, but was intended by the Scientific Advisory Panel to be implemented should number 3 be rejected by this Agency.)

(5) The Agency should prohibit the sale, distribution, or use of existing stocks of accessible chlordecone products following the effective date of cancellation.

B. Response of United States Department of Agriculture (USDA)

On January 11, 1977, the comments of the Secretary of Agriculture were transmitted to the Agency (2). USDA's response noted that, under FIFRA as amended, their responsibility is "in assessing the analysis of the overall impact of regulatory decisions on the ability to effectively control nuisance and damaging pest infestations as they may impinge on the agricultural economy, while preventing any unreasonable adverse effects on man or the environment." It was further noted that the insects controlled by chlordecone products are not of major concern in agricultural production but "are significant nuisances and potential health related pests" associated with farm buildings and farm households. The report stated that ants, roaches, and other household pests are a major concern in the processing of raw agricultural commodities and the storage of packaged and processed foods. The report limited itself to discussions of biological efficacy, benefit/risk, and exposure aspects of the use of chlordecone products.

USDA recommedations are listed below.

(1) Cancellation of Registrations

No specific recommendation was directed to this issue. However, if the USDA recommendation were adopted, that continued sale and use of end-use products be allowed into the indefinite future, these products would not be cancelled.

(2) Disposition of Existing Stock

(a) Inaccessible Products

The USDA report agreed with the Kepone Working Group's recommendation that the continued sale and use of these products be permitted, but it maintained that that there is "strong justification for not placing a time period on the availability and use of chlordecone for ant, roach and other household pest control." (This qualification apparently referred only to inaccessible products.)

(b) Accessible Products

The report stated that hazard to children from accessible products may be sufficient to warrant permitting continued use only under restrictive labeling both as to placement and to use by certified applicators.

(c) 25% Kepone Special Mixture Product (Manufacturing Use Only)

No specific recommendation. Again, however, if the comments directed to inaccessible and accessible products were incorporated in our recommendations, 25% Kepone Special Mixture would have to be available in order to formulate these products.

TABLE I. Comparison of Recommendations of EPA Kepone Working Group, the Department of Agriculture and the Scientific Advisory Panel

ISSUE	ORIGINAL RECOMMENDATIONS OF THE KEPONE WORKING GROUP & PESTICIDE CHEMICAL REVIEW COMMITTEE (PCRC)	RECOMMENDATIONS OF THE UNITED STATES OF AGRICULTURE (USDA)	RECOMMENDATIONS OF THE SCIENTIFIC ADVISORY PANEL (SAP)	MINORITY OPINIONS OF SAP MEMBERS
Whether to cancel	Issue notice of intent to cancel	Continue registrations	Agrees with Working Group and PCRC	
Disposition of 0.125% inaccessible bait products	Three year limit on formulation, the end of this time all remaining inaccessible products would be recalled by formulators and formulation of new products would cease.	Agrees with permitting continued formulation, that there is strong justification for not placing a limit on the availability of chlordecone products.	Permit sale and use for three those supplies of inaccessible products formulated at the time the cancellation is effective. Further formulation would not be permitted. Do not permit further formulation from manufacturing grade chlordecone.	Stop all further dissale, and formulation.
Disposition of 0.125% chlordecone accessible bait products	Prohibit formulation, sale, and use as of the effective date of cancellation. Request recall of existing stocks from retail level.	Hazard to children may be sufficient to warrant permitting continued use only 1) under restrictive labeling as to placement and 2) to use by certified applicators.	Agrees with Working Group and PCRC recommendations.	
Dispositions of 25% Kepone Special Mixture for Manufacturing Use only	Permit use for production of only inaccessible products for a three year period. Disallow use for formulation into accessible products as	The above recommendations would permit unlimited use should another source of chlordecone be found.	Disallow formulation sale and use of all existing stocks as of the effective date of cancellation.	Allow disposition consistant with the Working Group's recommenda-

of the effective date of cancellation. Those supplies of 25% Kepone Special Mixture for the latter use would be destroyed.

tions, but monitor formulating processes.

IV. SUMMARY OF EPA ANALYSIS AND RESPONSE TO COMMENTS FROM USDA AND SAP

A. Cancellation of All Existing Chlordecone Registrations

Only USDA objected to EPA's issuing a notice of intent to cancel remaining chlordecone registrations, and this objection was only tangential (see Table 1). The Working Group remains convinced that chlordecone poses a carcinogenic risk to man,[6/] and that the risks of continued exposure to man from existing chlordecone registered products outweigh the benefits.[7/] USDA's unsupported assertion to the contrary is rejected.

USDA's comments primarily address the benefits of chlordecone use. USDA states, "Use experience has demonstrated that many species of ants and roaches are more effectively controlled by using baits as either a supplement to other insecticides or as the sole formulation." Yet it presents no comparative efficacy testing or documentation of use experience which this Agency can assess. The USDA report further states that "should these pending actions result in the loss of use through cancellation or lack of availability to the general public by restricted use, the impact on effective control measures could be significant on the ability of homeowners to control their own pests." This appears to be an overstatement in light of the numbers of available alternatives (see Position Document 3, pp. 13-15, for CED benefit/risk analyses) and the failure of USDA to provide a measure of the impact on effective control measures and contrary to USDA's recommendation that accessible products be reclassified for restricted use.

The USDA also offers no supportive data for its statement, "Established use experience shows that when inaccessible containers or inaccessible placement are used, the bait displays a high degree of safety in handling with low potential for exposure to humans and animals." USDA stated that the health risks from the inaccessible products baits are "small," citing examples from Position Document 3. The Working Group agrees with this determination. USDA cited the absence of symptoms in children ingesting the contents of traps and the few reported cases of children actually opening the traps. While the absence of acute effects as manifested by the lack of symptoms is very

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6/ Chlordecone also poses other risks to man that are detailed further in this section, infra.

7/ On this point the Scientific Advisory Panel is in unanimous agreement. On Page 1 of its response it states: "The Panel unanimously agrees that continued registration and use of these pesticides appear to pose substantial questions of safety amounting to an unreasonable risk to man and the environment."

important, the chronic effects of chlordecone exposure are of most concern to the Agency and are the basis for this rebuttable presumption.

The Agency has determined that unlimited sale, distribution and use of any currently registered end-use chlordecone products into the indefinite future would increase the risk of oral, dermal, and inhalation exposure without a corresponding increase in benefits. No new evidence has been presented which would cause the Agency to reverse this position.

B. Use of Manufacturing-Use-Only Chlordecone to Formulate Inaccessible Chlordecone Products.

The proposed notice of intent to cancel and the corresponding amendment of the notice of cancellation of Allied's registrations would have allowed formulators of inaccessible traps to use existing stocks of Allied's manufacturing-use-only chlordecone to formulate additional inaccessible chlordecone products. USDA agreed with this proposal. The Scientific Advisory Panel disagreed with this proposal, and it recommended that "EPA institute efforts to recover and dispose of all nonformulated stocks of this material in a safer manner" (pg. 2). The EPA accepts the recommendation of the Scientific Advisory Panel for the reasons given by the Scientific Advisory Panel and for other reasons as listed below.

(1) Disposal.

In recommending allowing use of existing stocks of manufacturing grade chlordecone for formulation into inaccessible products, the Working Group was strongly motivated by the problems engendered by attempts to dispose of manufacturing grade chlordecone (See Position Document 3, p. 10). It was generally the opinion of the Working Group that the risks to man and the environment arising from improper disposal of existing stocks of manufacturing grade chlordecone were greater than the risks from the use of inaccessible products formulated from existing stocks of manufacturing grade chlordecone. This situation has changed dramatically in light of the recent enactment of the Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976 (PL 94-580).

Section 7003 of the Resource Conservation and Recovery Act provides that:

> Notwithstanding any other provision of this Act, upon receipt of evidence that the handling, storage, treatment, transportation or disposal of any solid waste or hazardous waste is presenting an imminent and substantial endangerment to health or the environment, the Administrator [of EPA] may bring suit on behalf of the United States in the appropriate district court to immediately restrain any person for contributing to the

alledged disposal to stop such handling, storage, treatment, transportation, or disposal or to take such other action as may be necessary.

The above provision gives the Agency authority to protect against improper disposal of manufacturing grade chlordecone. The Working Group is now of the opinion that the risks to man and the environment from proper disposal of existing stocks of manufacturing grade chlordecone are diminished and the use of existing stocks of manufacturing-use-only chlordecone to formulate inaccessible products is unwarranted.

(2) Risks to Man Other than Oncogenicity

The Scientific Advisory Panel stressed that in addition to oncogenic risks, it was concerned about other adverse affects of chlordecone (e.g., neuromuscular, behavioral, reproductive, and mutagenic effects). While the Working Group cannot at this stage of the process explore these potential risks thoroughly, it is aware of information that supports the Scientific Advisory Panel's concern.[8/] On this basis, the Working Group is of the opinion that the risks posed by these additional effects constitute a further reason for cancelling all remaining chlordecone registrations and for changing its recommendation so as to forbid use of existing stocks of manufacturing grade chlordecone for formulating additional end use products.

(3) Amount of Chlordecone Held by Registrants

The Working Group's original recommendation was made on the basis of a high estimate, derived from an incomplete June 1976 registrant response, of 537.8 lb of actual chlordecone in the possession of current registrants. Of this amount, it was speculated that 22.8 lb was formulated into 0.125% chlordecone baits for end-use, and the remainder was 25% Kepone Special Mixture for formulation into 0.125% end-use products.

At the time, the estimated 537.8 lb actual chlordecone was assumed to be a conservative estimate which sufficiently overstated the amount of chlordecone held by registrants to account for all chlordecone in the channels of trade.

8/ Tremors in laboratory rodents at dosage levels lower than those observed to cause tumors were observed in both of the oncogencity studies used as a basis for issuance of the RPAR (3), (4). Several laboratory studies have also shown significant reductions in reproduction in laboratory mice fed chlordecone at dosages ranging from 5 to 37.5 ppm (5), (6).

In humans, massive doses of chlordecone absorbed by production workers have resulted in tremors and in absent or decreased sperm count with markedly decreased motility.

A more recent February 1977 inquiry, however, by the Regional Offices of the Office of Pesticide Programs' Office of Enforcement has revealed that at a minimum 9/ the following amounts of chlordecone are currently held by registrants (7):

Type of product	Total lb of product	Total lb of chlordecone
.125% Kepone enclosed metal and plastic traps ("inaccessible" product)	52,809 +13,680 in process	66.01 17.1
.125% Kepone unenclosed end-use products ("accessible " product)	13,850	18.05
.125% Kepone enclosed foil packages. ("accessible" product) (One firm formulates a .106% Kepone product.)	6,686	7.12
Allied 25% Kepone Special Mixture for manufacturing-use only	1,968	492
10% Kepone mixture in the formulation process (Manufacturer reports end-use product not yet determined)	600	60
Total	89,594	660.28

9/ Two small formulating companies have not as yet responded, and another has submitted an incomplete report.

The 660.28 lb of chlordecone in process and in end-use and manufacturing-use products known to be held by registrants is more than the highest estimate of 537.8 lb of actual chlordecone in these products which was used in calculations of the oncogenic risk. Although the amount of chlordecone in the 25% Kepone Special Mixture is slightly less than previously supposed, there is far more chlordecone in end-use products and in the formulation process than was estimated, thereby significantly increasing the potential environmental burden.

C. Use of Existing Stocks of Acessible Products

The Working Group concurs with the Scientific Advisory Panel in its recommendation not to allow further formulation of accessible chlordecone products and to prohibit from the effective date of cancellation all further sale, distribution, or use of existing accessible chlordecone products.

The Working Group is of the opinion that USDA's suggestion that the safe use of accessible chlordecone products can be accomplished either through appropriate label restrictions or through application by certified applicators cannot adequately protect children from exposure to chlordecone. Label changes will not ensure that the instructions are followed within the household. Moreover, USDA offers no suggestions for how EPA, either using label changes or certified applicators, could ensure that accessible products would be removed from the reach of children and at the same time perform their pesticidal function adequately. Finally, label changes and use by certified applicators will not protect against general environmental contamination (See part B.3 supra) nor will these restrictions affect the safety of workers exposed during the manufacturing process.

D. Use of Existing Stocks of Inacessible Chlordecone Products

The Kepone Working Group originally selected 3 years as a termination date for formulation, packaging, and sale of these products because that period was considered adequate to allow for the conversion into end-use inaccessible traps of all 25% Kepone Special Mixture intended for that purpose and the exhaustion through sale and use of all stocks of these end-use products.

The oncogenic effect of chlordecone was the only chronic health hazard assessed by the Agency when making this determination. As USDA has stated in their comments, EPA determined that there is not a significant risk of cancer to children via the inhalation route from the inaccessible products. Dermal and oral exposure was also judged to be low. Risk analyses determined that an extremely small number of carcinomas would likely result from any expected ingestion of the contents of traps by children (See Position Document 3, pp. 12-15).

The benefit analysis determined that chlordecone baits did provide a minor benefit of convenience to homeowners in the control of ants and roaches. These analyses were predicated, however, upon the cancellation and eventual exhaustion of supply of these products and not upon the continued unlimited production, sale and use which might result if these products were not cancelled.

The majority of the Scientific Advisory Panel agreed with the Working Group's recommendation to permit the sale and use of these existing stocks of products for 3 years. SAP believed, as did the Working Group, that even given possible adverse health effects in addition to oncogenicity, the use of these products for that time period would not have unreasonable adverse effects on the environment. A minority SAP comment, however, stated opposition to this use on the basis of dispersal of chlordecone from the traps by ants and roaches, and the hazard from waste disposal of discarded containers in incinerators and landfills.

Scientists of the Criteria and Evaluation Division, Office of Pesticide Programs and Carcinogen Assessment Group (EPA) in their analyses and the Working Group in its determination considered these aspects of the problem in reaching their conclusions.

The original recommendation of the Kepone Working Group permitting sale for 3 years was based on a "worst case" assumption that 13,772,800 1/4 oz inaccessible plastic or metal traps could be formulated from the 25% Kepone manufacturing use product earmarked for that purpose (assumed to be 1/2 the total amount of 25% Kepone Special Mixture estimated to be held by formulators in addition to those traps already made). The recent formulator survey reported that there are 1,405,935 already formulated inaccessible traps ranging in weight from 1 oz to 1/6 oz with one firm reporting enough material in process to formulate an additional 1,313,280 1/6-oz inaccessible traps. The amount of actual chlordecone in these 2,719,215 individual traps is calculated to be 83 lb. Adding the 60 lb of actual chlordecone in the 600 lb. of 10% chlordecone held by one formulator, this still constitutes an amount far less than the previously estimated 268 lb of chlordecone which might have been used in these products had the Working Group's original recommendations been followed.

Registrants have been notified that further formulation of the cancelled Allied 25% Kepone Special Mixture is illegal. Registrant firms will be monitored to ensure that this formulation does not occur.

Prevention of any further conversion of 25% Kepone Special Mixture to end-use products will thus further limit the amount of these products available to the public and therefore limit the public exposure and risk.

For all of the above reasons, the Working Group recommends that sale and use of only those inaccessible traps already formulated at the effective date of cancellation of these products be permitted and that there will be no time restriction on sale and use of these products.